DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 30, 2014

GI View, Ltd.
% Mark Heller
Partner
Goodwin Proctor, LLP
901 New York Avenue, NW
Washington, DC 20001

Re: K141286
Trade/Device Name: Aer-o-scope Colonoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: August 15, 2014
Received: August 15, 2014

Dear Mark Heller,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141286

Device Name
Aer-O-Scope™

Indications for Use *(Describe)*
The Aer-O-Scope Colonoscope System is intended to provide panoramic (360o) visualization (via a video monitor) and visual access to the adult lower gastrointestinal tract, (including but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy.

The Aer-O-Scope Disposable Scanner (colonoscope component of the Aer-O-Scope Colonoscope System) is a single use disposable device. An Aer-O-Scope ™ Scanner cannot be reprocessed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Summary Date: March 27, 2014

Device Name, 21 CFR 807.92(a)(2)

Trade Name: Aer-O-Scope Colonoscope System

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21 CFR § 876.1500

Product Code: FDF

Predicate Device, 21 CFR 807.92(a)(3):

Trade Name: Invendo C20 Colonoscopy System

510(k) Number: K100624 and K121582

Common Name: Colonoscope

Classification Name: Endoscope and accessories, 21CFR 876.1500

Product Code: FDF

Device Description, 21 CFR 807.92(a)(4)

The Aer-O-Scope Colonoscope System is a flexible, operator-controlled, colonoscope that utilizes a propulsion mechanism to provide visualization and visual (diagnostic) access to the colon. It is comprised of two major components, the Controlling Work Station and the Aer-O-Scope Disposable Scanner (the colonoscope component). The work station system console contains all internal components and subsystems required for operation and control of the Aer-O-Scope Colonoscope System, including a joystick component for controlling scope tip deflection. The Aer-O-Scope Disposable Scanner includes a soft narrow multilumen tube with channels for irrigation, insufflation, suction, CO_2 delivery to the balloons and colon, soft balloons for the propulsion system and an optical imaging head with a CMOS chip and lenses for both forward visualization and a 360° panoramic omni view. All commands are controlled by the operator and regulated through the Controlling Work Station.

Similar to the predicate device, the Aer-O-Scope Colonoscope System utilizes a propulsion system for colonic intubation and scanning. The propulsion system relies on CO_2 gas and soft pliable balloons that allow the Aer-O-Scope scanner to travel through the colon without the need for pushing force. A rectal balloon that sits at the base of the rectum and acts as a sealer prevents gas from escaping via the rectum. Two other balloons at the tip of the scope act as driving balloons. The space between the rectal balloon and the driving balloons is filled with low pressured CO_2 gas via the rear channel through the rectal introducer that helps move the optical imaging head forward. For retraction, the gas behind the driving balloons is vented via the two-way rear channel in the rectal introducer. The space between the cecum and the driving balloons is filled with low pressure CO_2 gas via the front channel, easing the driving balloons back towards the rectum. The tip of the scope with the optical imaging head can be deflected in any direction to ensure full visualization.

The Aer-O-Scope Disposable Scanner is a single use device and cannot be reprocessed. The main materials that come in contact with the patient are polyurethane and Pebax™ that are coated with a hydrophilic coating. The Aer-O-Scope Disposable Scanner has been demonstrated to be

biocompatible according to the ISO 10993 harmonized and FDA consensus standard.

Aer-O-Scope Controlling Work Station Specification Chart:

Item	Sub System	Output
Computer	Operating System	Windows XP Professional
Video System	Camera Type	CMOS (1.3 Megapixels)
	Screen Resolution Support	1600*1200; 1920*1080; 1920*1200
	Screen ratio Support	4:3; 16:9; 16:10
	Video Output Format	RGB
	Video Output Connector	DVI
	Light Intensity Adjustment	Automatic
Pneumatic System	Maximal Input Pressure	4.5 Bar
	Maximal Output Pressure	60 mBar
Power Requirements	Voltage	100-240V
	Frequency	50/60Hz
	Fuses	6.3A for 115VAC
Measurements	Work Station weight	167kg
	Work Station dimensions	1200 mm (H) * 400 mm (W) * 600 mm (D)

Aer-O-Scope Disposable Scanner Specification Chart

Item	Sub-system	Output
Optical Head	Sensor	1280 * 1024 CMOS sensor
	Depth of Field - OMNI	11-50 mm
	Depth of Field - Front	10-60 mm
	Field of View - OMNI	front tilt 30° - back tilt 40°
	Angular Field of View - OMNI	360°
	Field of View - Front	90°
	Tip Deflection – All Directions	160°
	Multi-lumen Working Length	2000 mm
	Multi-lumen Total Length	2300 mm
	Optical Imaging Head Length	42 mm
Optical Head and Multi Lumen tube Width	Diameter of insertion point - optical head	13 mm
	Multi Lumen maximal diameter	7.5 mm
Pneumatic System	Insufflation Air Pressure	70 mBar
	Insufflation Air Flow Rate	3 liter/min
	Rectal Balloon maximal pressure	60mb
	Main and front balloon maximal pressure	60mb

Predicate Comparison, 21 CFR 807.92(a)(6)

The Aer-O-Scope Colonoscope System has the same intended use as the predicate Invendo C20 Colonoscopy System (K100624 and K121582) of examining the colon or rectum, *see* 21 CFR § 876.1500, product code FDF. While the Invendo C20 Colonoscopy System is indicated for visualization and therapeutic access, the Aer-O-Scope Colonoscope System is indicated only for visualization and visual (diagnostic) access to the colon. Both systems are indicated for adult populations who may undergo colonoscopy in physicians' clinics, ambulatory surgical centers and hospital settings. Because the Aer-O-Scope Colonoscope System provides only visual (diagnostic) access to the colon, it is not indicated for endoscopic surgery.

Indications for Use Comparison:

Aer-O-Scope Colonoscope System Indications for Use Statement	Invendo C20 Colonoscopy System Indications for Use Statement
The Aer-O-Scope Colonoscope System is intended to provide panoramic (360°) visualization (via a video monitor) and visual access to the adult lower gastrointestinal tract, (including but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy. The Aer-O-Scope Disposable Scanner (colonoscope component of the Aer-O-Scope Colonoscope System) is a single use disposable device. An Aer-O-Scope Scanner cannot be reprocessed.	The Invendo C20 Colonoscopy System is intended to provide visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract (including but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery. The colonoscope component of the Invendo C20 Colonoscopy System, the SC20 colonoscope, is a single use disposable device. The SC20 colonoscope cannot be reprocessed.

The Aer-O-Scope's indications are a subset of the predicate device's indications, and the results of bench, pre-clinical and clinical testing demonstrate that the minor technical differences between the Aer-O-Scope and its predicate raise the same types of safety and effectiveness questions, and do not adversely affect the Aer-O-Scope's safety and effectiveness profile compared to the predicate.

The Aer-O-Scope Colonoscope System has many features in common with the currently marketed Invendo C20 Colonoscopy System and with other currently marketed conventional colonoscopes.

Like the predicate device, the Aer-O-Scope Disposable Scanner (the colonoscope component) is a long flexible endoscope with optics at the deflectable tip of the device and openings for irrigation, insufflation and suction. The Aer-O-Scope Disposable Scanner uses an overtube mechanism to facilitate easier insertion into the recto-sigmoidal junction. The Invendo C20 Colonoscope also uses an overtube mechanism.

The Aer-O-Scope Colonoscope System, like the Invendo C20 Colonoscopy, consists of two components, the Controlling Work Station and a disposable colonoscope component (the Aer-O-Scope Disposable Scanner). The Aer-O-Scope Controlling Work Station supplies and controls the Aer-O-Scope Disposable Scanner according to user commands via a keyboard or buttons on the steering joystick. The distal tip of the Aer-O-Scope Disposable Scanner is deflectable (controlled by the mechanical joystick on the controlling work station) and equipped with a CMOS camera and LEDs for Illumination. Like the predicate, the Aer-O-Scope Colonoscope System is

equipped with insufflation, irrigation and suction functions. Deflection, rinsing, insufflation and suction are activated and controlled by the Controlling Work Station, in accordance with operator commands.

Like the Invendo C20 Colonoscopy System, the Aer-O-Scope Disposable Scanner is not pushed or otherwise directly manually manipulated by the operator. The Aer-O-Scope Disposable Scanner moves through the colon with the aid of a propulsion system and under the direction and control of the operator using a joystick. The propulsion system relies on the use of balloons, an ultra-flexible multi-luminal cable and low, controlled pressures of CO_2 gas to move the optical imaging head at the tip of the Aer-O-Scope Disposable Scanner inward towards the cecum and then outwards for scanning the colon. While the exact propulsion mechanism is different from that of the Invendo C20 Colonoscopy System, it is similar in that it removes the necessity for manual manipulations and use of pushing force by the operator. In addition, the results of bench, pre-clinical and clinical testing show that the differences in the propulsion systems raises the same types of safety and effectiveness questions as compared to the Invendo C20 Colonoscopy System and that the Aer-O-Scope Colonoscope System is as safe and effective as its cleared predicate device.

Both the Invendo C20 Colonoscope component and the Aer-O-Scope Colonoscope component are disposable. The Aer-O-Scope Joystick is connected to the Controlling Workstation as is the hand held control of the Invendo C20 colonoscope to the base unit. Both the Invendo C20 base unit and the Aer-O-Scope Controlling Work Station contain an articulated arm with the hand held controller at the end allowing for optimal accessibility (positioning) to the patient.

The tip of the Aer-O-Scope Disposable Scanner can be deflected using the mechanical joystick. The mechanism used for deflection is different than that of the Invendo C20 Colonoscopy System; however, the results of bench, pre-clinical and clinical testing demonstrate that the differences raise the same types of safety and effectiveness questions as compared to the cleared predicate device.

Both the Aer-O-Scope Colonoscope System and the predicate device use a CMOS camera at the tip of the scope and LEDs for illumination. The Aer-O-Scope™ Colonoscope System provides a higher sensor resolution than the predicate device. The Aer-O-Scope Colonoscope System video output shows both a forward view, similar to the Invendo C20 colonoscope. The Invendo C20 colonoscope's video output has a front view of the colonic mucosa. The

Aer-O-Scope Colonoscope System shows both a front view and a 360° panoramic view of a cross section of the colonic mucosa, both slightly ahead and to the area behind the optical imaging head. While the Aer-O-Scope video output is different in terms of the views that are provided, the results of the bench, pre-clinical and clinical testing demonstrate that these differences raise the same types of safety and effectiveness questions as compared to the cleared predicate device. In essence, the Aero-Scope provides the same view as the Invendo C20 colonoscope, and provides an additional panoramic view.

The materials used in the Aer-O-Scope Colonoscope System are different from those of the predicate device; however, complete biocompatibility data demonstrate that the new device is at least as safe and effective as the predicate.

Clinical data confirm that the Aer-O-Scope Colonoscope System can navigate the colon and visualize abnormalities.

The Aer-O-Scope™ Colonoscope System raises the same types of safety and effectiveness questions as the predicate device. Additionally performance data demonstrate that the Aer-O-Scope Colonoscope System is at least as safe and effective as the predicate device; therefore, the Aer-O-Scope Colonoscope System is substantially equivalent to the Invendo C20 Colonoscopy System.

Performance Data – Bench, 21 CFR 807.92(b)(1):

GI View Ltd. conducted bench tests to measure forces during device use, biocompatibility of device components and safety. In all instances the Aer-O-Scope Colonoscope System functioned as intended and met the individual test specifications.

Forces measured were less than the force needed to cause a perforation as determined by the professional literature.

Biocompatibility tests were performed and met all of the required criteria.

EMC and Electrical safety were tested and found compliant with the applicable standards.

Animal studies were performed to show safety. In addition a visualization study was performed comparing the Aer-O-Scope Colonoscope System to a conventional colonoscope.

Performance Data – Clinical, 21 CFR 807.92(b)(2);

A clinical study was carried out in the Tel Aviv Medical Center. 56 patients (18 training cohort and 38 study cohort) underwent Aer-O-Scope colonoscopy followed by conventional colonoscopy. The primary safety endpoint was frequency and severity of adverse device effects (ADEs) using the Aer-O-Scope for all subjects (training and study).
The primary efficacy objective was cecal intubation in 90% of all study cases.
The secondary endpoints asked operators to evaluate the ease of use and visualization using the Aer-O-Scope based on their experience with conventional colonoscopes.
Two tertiary objectives were set forth in the clinical investigational plan. The first objective was to observe the number of Aer-O-Scope Colonoscopies needed to acquire proficiency in device operation, and was intended to aid the sponsor in developing a training program. The second objective was to document the number of pathologies visualized during procedures. This tertiary objective was intended as an observational endpoint.

This study called for tandem colonoscopy using the Aer-O-Scope Colonoscope for the first procedure and a conventional colonoscope for the second procedure to monitor for any mucosal damage during treatment with the experimental device. During the course of this investigation, there were no reportable adverse events or adverse device effects during the course of this study.

In the pooled sample size of 56 subjects, the success rate was 98.2% for cecal intubation and the lower boundary of the 95% confidence interval was 90.4%. One Aer-O-Scope procedure in the training cohort did not reach the cecum. This was attributed to insufficient colonic preparation which led the physician to wrongly conclude that he reached the cecum. While this was not a comparative study it should be noted that the cecal intubation rate for the conventional colonoscope in the pooled sample size of 56 subjects was also 98.2%. One patient in the study cohort was not intubated to the cecum with the conventional colonoscope due to poor colonic prep but was intubated to the cecum with the Aer-O-Scope Colonoscope.

Summary, 21 CFR 807.92(b)(3);

The bench tests included studies related to forces, biocompatibility, constructive and electrical safety and demonstrated that the Aer-O-Scope Colonoscope System performed as well as the predicate device. The clinical data also demonstrated that the Aer-O-Scope Colonoscope System can successfully provide a simple visualization tool for the adult lower gastrointestinal tract for screening endoscopy (colonoscopy).